



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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**PURGED** *RAK*

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

cc: HFI-35/FOI Staff  
DWA

January 13, 1997

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 97-25

Loretta Robertoy  
President  
Hyline Orchards  
8240 Highway 42  
Fish Creek, Wisconsin 54212

Dear Ms. Robertoy:

An inspection of your firm located at 8240 Highway 42, Fish Creek, WI, by Wisconsin Department of Agriculture, Trade and Consumer Protection Inspector Nancy Smit on November 18, 1996, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for acidified food [Title 21, Code of Federal Regulations, Part 114 (21 CFR 114)]. Such conditions cause the food products being manufactured at this facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

The following deviations were noted:

- 21 CFR 114.800(a)(2)      Sufficient control, including frequent testing and recording of results, shall be exercised so that the finished equilibrium pH values for acidified foods are not higher than 4.6. If the finished equilibrium pH is 4.0 or below then the measurement of acidity of the

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final product may be made by any suitable method. Since the finished equilibrium pH of your "Bread and Butter Pickles" and "Hot Dilly Vegie's" are below 4.0 you may use pH indicator paper. However, the range should be narrow as possible. Indicator papers with a range of  $\pm 0.25$  pH units are available.

21 CFR 114.80(b)

Each container or product shall be marked with an identifying code permanently visible to the naked eye. The required identification shall specify in code the establishment where the product was packed, the product contained therein, and the year, day and period during which it was packed. The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Your codes only refer to the date the product was packed.

21 CFR 114.83

The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.

21 CFR 114.100

None of your records required by this section are satisfactory. The daily processing record forms you are using are for still retorts. At a minimum the column heading will have to be modified. The information recorded should also be accurate and complete. For example, the recorded pH values are not accurate since the pH indicating paper you are using can only be estimated to  $\pm 0.5$  pH units and you are reporting a value of      In addition, is this the finished equilibrium pH? The process temperatures being reported are      °F and      °F. An open, boiling water bath cannot exceed a temperature of 212°F at sea level. The processing dates are not always recorded. Distribution records must also be maintained.

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Processes must be filed for all acidified foods that are stored, distributed and retailed without refrigeration (21 CFR 108). The following five products may require a filed process if the pH of the raw materials, e.g. asparagus, is above 4.6 and the products are not naturally fermented.

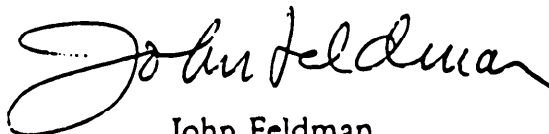
- Asparagus Pickles
- Hot Polish Dill Pickles
- Hot Dilly Vegie's
- Old Fashioned Dill Pickles
- Cucumber Cherry Pickles

The formulation for "Bread and Butter Pickles" contains onions. The ingredient statement does not list onions as an ingredient. Onions must be declared in the ingredients statement. Items listed in the ingredient statement are to appear in descending order or predominance by weight (21 CFR 101.4). Your firm may or may not have to apply for an exemption from the Nutrition Labeling and Education Act (NLEA). Enclosed are the regulations governing the exemptions for small businesses.

The above cited violations are not intended to be an all-inclusive statement of the deficiencies which may exist at your firm. It is your responsibility to ensure that your firm is in compliance with all requirements of the Act. You should take prompt action to correct these deviations. Failure to promptly correct them may result in further action such as seizure and/or injunction without further notice. Enclosed are pertinent parts of the regulations.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely yours,



John Feldman  
Director  
Minneapolis District